

**REQUEST FOR EXTENSION OF TIME**

It is respectfully requested that the period for reply to the August 27, 2002 Office Action be extended one month, i.e., to up to and including October 28, 2002 (as October 27, 2002 is a Sunday). Submitted herewith is a check for \$110.00 in payment of the fee therefor; and, the Commissioner is hereby authorized to charge any additionally required fee for the extension, or any other fee occasioned by this paper, or credit any overpayment in such fees, to Deposit Account No. 50-0320.

**REMARKS**

Reconsideration and withdrawal of the restriction requirement and the requirements for elections of species are respectfully requested in view of the remarks and attachments herewith.

The August 27, 2002 Office Action required an election under 35 U.S.C. § 121 from:

**Group I.** Claims 1-14, drawn to a DNA vaccine comprising a naked DNA encoding an antigenic polypeptide and one adjuvant compound which is the polymers of acrylic or methacrylic acid, classifiable in class 514, subclass 44; and

**Group II.** Claims 1-14, a DNA vaccine comprising a naked DNA encoding an antigenic polypeptide and one adjuvant compound which is the copolymers of maleic anhydride and alkenyl derivative, classifiable in class 424, subclass 486.

The August 27, 2002 Office Action requires an election of species from among allylsucrose and allylpentaerythritol and also requires an election from among the specific named pathogens listed in claim 9.

The invention of Group I, claims 1-14 drawn to a DNA vaccine comprising a naked DNA encoding an antigenic polypeptide and one adjuvant compound which is the polymers of acrylic or methacrylic acid, is elected, for further prosecution in this application. This election is made *with traverse* and is made without prejudice to Applicants' right to file divisional applications directed to the non-elected subject matter. It is respectfully requested that the restriction requirement be favorably reconsidered and withdrawn.

The species allylsucrose is also elected. This election is also made *with traverse* as the species are each related to one another and directed to the same inventive concept and are capable of being simultaneously searched. Further, the species equine influenza virus, recited in

claim 9, is elected. This election is also made *with traverse* as the species are each related to one another and directed to the same inventive concept.

It is understood that the Examiner can broaden the search to include other species, e.g., upon determining that a species is allowable, or as discussed herein, when there is a relationship among the species and/or number of species is not too great. It is understood that upon the allowance of a generic claim, Applicants will be entitled to consideration of claims to additional species which are written in dependent form or which otherwise include all of the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141.

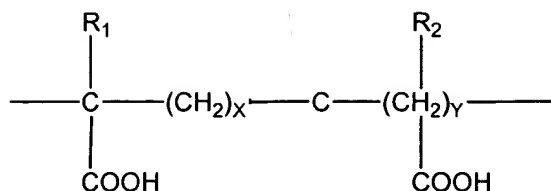
It is respectfully urged that the Restriction Requirement and the species election requirements do not establish that searching all the inventions would constitute an undue burden to the Examiner or the Patent Office. Moreover, it is urged that the Restriction Requirement and the species election requirements are contrary to public policy. Accordingly, it is respectfully submitted that the Restriction Requirement and the species election requirements are improper and should be withdrawn or at least modified.

The M.P.E.P. lists two criteria for a proper restriction requirement. First, the invention must be independent or distinct. M.P.E.P. § 803. Second, searching the additional invention must constitute an undue burden on the examiner if restriction is not required. *Id.* The M.P.E.P. directs the examiner to search and examine an entire application “[i]f the search and examination of an entire application can be made without serious burden, ... even though it includes claims to distinct or independent inventions.” *Id.*

It is urged that the Restriction Requirement does not meet the second of these criteria as the search for all of the groups overlaps.

In sum, there is no basis in fact or law for separating the claimed subject matter on the basis of the chemical structure of the adjuvants.

The polymers of acrylic acid, the polymers of methacrylic acid and the copolymers of maleic anhydride and an alkenyl, e.g., ethylene, are polymers having monomeric units of the formula:

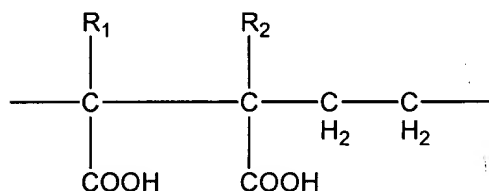


in which  $\text{R}_1$  and  $\text{R}_2$  are identical or different and are H or  $\text{CH}_3$ ;  $x$  is 0 or 1;  $y$  is 1 or 2; and  $x+y=2$ .

Clearly, the polymers of acrylic acid, the polymers of methacrylic acid and the copolymers of maleic anhydride and an alkenyl, e.g., ethylene, are structurally related: When  $x=1$  and  $y=1$  the polymers are carbomers, acrylic acid or methacrylic acid polymers; and, when  $x=0$  and  $y=2$ , the polymers are copolymers of maleic anhydride and an alkenyl, e.g., ethylene.

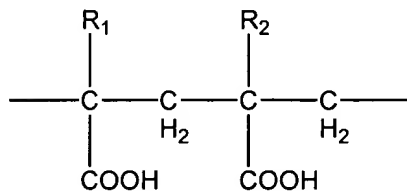
The copolymers of maleic anhydride and an alkenyl, e.g., ethylene, and the polymers of methacrylic acid and acrylic acid differ by the positioning of  $\text{CH}_2$ .

More specifically, in the above formula, when  $x=0$  and  $y=2$  and the polymers are copolymers of maleic anhydride and an alkenyl, e.g., ethylene, the polymers have monomeric units of the formula:



in which  $\text{R}_1$  and  $\text{R}_2$  are identical or different and are H or  $\text{CH}_3$ .

Similarly, in the above formula, when  $x=1$  and  $y=1$  and the polymers are carbomers, i.e., acrylic acid or methacrylic acid polymers, the polymers have units of the formula:



in which  $\text{R}$  and  $\text{R}$  are H (acrylic) or  $\text{CH}_3$  (methacrylic).

Clearly, there is no basis in law or fact for the restriction requirement based on the adjuvants as the copolymers of maleic anhydride and an alkenyl, e.g., ethylene and the polymers of methacrylic acid and acrylic acid differ by the positioning of  $\text{CH}_2$ .

Thus, searching and examining Groups I and II—*i.e.*, searching and examining DNA immunogenic compositions wherein the adjuvant has the above formula—presents no undue or serious burden on the Examiner. There is no undue or serious burden to search and examine copolymers of maleic anhydride and an alkenyl such as ethylene, polymers of acrylic acid and methacrylic acid, *i.e.*, Groups I and II.

Therefore, it is respectfully requested that Groups I and II be rejoined, as there is believed no basis in law or fact for restriction between Groups I and II.

It is respectfully urged, therefore, that restricting the claims in the manner suggested in the Restriction Requirement constitutes an undue burden to Applicants as well as to the public. The cost of prosecuting and maintaining so many patents is unreasonable in view of the fact that the two groups are so closely related. Further, the public is inconvenienced as they will not know whether or not Applicants will file a divisional application to the remaining subject matter. Thus, the public will not know if they can practice the remaining invention without infringing future patent applications.

With regard to the election of species requirement, the Examiner is respectfully requested to review M.P.E.P. § 808.01(a) which states that “where there is no disclosure of relationship between species (*see* M.P.E.P. § 806.04 (b)), they are independent inventions and election of one invention” is required (July 1998). In view of M.P.E.P. §803, however, when the generic claim includes sufficiently few species that a search and examination of all the species at one time would not impose a serious burden on the examiner, then a requirement for election is inappropriate.

In view of the above, reconsideration and withdrawal of the requirement for restriction and election of species requirements are respectfully requested.

The Office Action identifies that claims 1-14 are generic to a plurality of disclosed species, and requires an election of a single disclosed species for search purposes. The Office Action called for an election of species from between, allylsucrose and allylpentaerythritol, with allylsucrose herein elected with traverse; and, it being understood that the Examiner can broaden the search to include other species, *e.g.*, upon determining that a species is allowable, or as discussed herein, when there is a relationship among the species and/or number of species is not too great.

The species of allylsucrose and allylpentaerythritol are few in number—there are only two (2). Thus, they can be searched without serious burden. Carbomer or Carbopol is an acrylic acid polymer crosslinked with either allylsucrose or allyl ethers of pentaerythritol, *i.e.* the crosslinking agent for the Carbopol or carbomer polymer is either allylsucrose or allylpentaerythritol (see attachments, Pharmacopée Européenne 2899-2901; Handbook of Pharmaceutical Excipients (3d ed. 2000)). Moreover, the terms carbomer and Carbopol can be used in simple Boolean searches, such that there is clearly no undue burden in searching and examining both species. Accordingly, searching and examining carbomer or Carbopol will encompass both species.

Furthermore, Patent Office Policy endorses that the proposed search include both species—allylsucrose and allylpentaerythritol. For example, U.S. Patent 5,853,715, claim 7, is directed to an adjuvant that is, *inter alia*, Carbopol (see attachment). As this patent shows, it is not an undue burden for the Patent Office to search claims that contain Carbopol or carbomer—both species—as adjuvant.

Therefore, the request for species election as to allylsucrose or allylpentaerythritol should be reconsidered and withdrawn, and such relief is respectfully requested.

Further, the Office Action seeks an election from among the specific named pathogens listed in claim 9 and requires a single disclosed species for search purposes. Equine influenza virus is elected with traverse, for further prosecution.

As noted above, when the generic claim includes sufficiently few species that a search and examination of all the species at one time would not impose a serious burden on the examiner, then a requirement for election is inappropriate. The species listed in claim 9 are not too great in number; they can be searched without serious burden. At the very least, the group of equine pathogens including: equine rhinopneumonia virus, equine influenza virus, Cl. Tetani, Eastern encephalitis virus, Western encephalitis virus, Venezuelan encephalitis virus, B. burgdoferi and rabies virus could be searched and examined together. Therefore, the request for species election should be reconsidered and withdrawn, or regrouped, e.g., so that all equine pathogens are searched and examined together in this application.

It is also respectfully urged that restricting the claims in the manner suggested in the election of species requirement constitutes an undue burden to the Applicants. If followed, the


election of species requirement would require Applicants to file a number of additional applications. The cost of prosecuting and maintaining additional patents is unreasonable in view of the fact that the application as filed includes claims that are all related to one another. Further, under GATT, the period of exclusivity for any patents that issue from these divisional applications is greatly reduced. In addition, the public is inconvenienced, as it will not know whether or not Applicants will file divisional applications to the remaining subject matter. Accordingly, the public will not know if they can practice the remaining invention without infringing future patent applications.

Therefore the request for election of species as to claim 9 should be reconsidered and withdrawn or reformulated, and such relief is respectfully requested.

In view of the above, reconsideration and withdrawal of the requirement for restriction and election of species requirements are respectfully requested.

Respectfully submitted,  
FROMMER LAWRENCE & HAUG LLP

By:



Thomas J. Kowalski

Reg. No. 32,147

Telephone: (212) 588-0800

Facsimile: (212) 588-0500